REMARKS

Claims 1-5, 8-15, 17, 37 and 40-42 are presently pending herein.

Claim 1 has been amended to further clarify that the pharmaceutically acceptable suspension is introduced into an endoluminal drug delivery catheter for delivery to a patient. Support for the amendment of claim 1 can be found throughout the specification. See, e.g., paragraph [0034] and paragraphs [0047] to [0050]. No new matter is added.

The Office Action indicates that claims 4 and 5 are withdrawn from consideration as directed to non-elected species. However, claims 4 and 5 have not been deleted at this time because, as indicated in the Office Action mailed July 16, 2002, the restriction requirement between the linked inventions is subject to the non-allowance of the linking claim (e.g., claim 1).

Rejection of Claims 1-3, 7-15, 17, 37, 40-42 under 35 U.S.C. 102(e)—Pinchuk et al.

Claims 1-3, 7-15, 17, 37, and 40-42 are presently rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0107330 (Pinchuk et al.).

Applicants respectfully traverse this rejection and its supporting remarks.

For example, the Office Action states, *inter alia*, that "[t]he teaching of a suspension comprising the block copolymers and a therapeutic agent, wherein the copolymer and therapeutic agents are both present or commingled in a buffered solution before being exposed to a medical device, is clearly taught on page 9, paragraph 0190, and paragraph 0196."

Applicants disagree. Paragraph 0190 actually reads as follows (emphasis added):

> If desired, the copolymer/solvent mixture can contain more than one *solvent* (for example, one *solvent appropriate for the block copolymer* and a different solvent appropriate for the therapeutic agent). As a specific non-limiting example, where paclitaxel is selected as a drug and where the copolymer is the triblock polystyrene-polyisobutylene-polystyrene, a *solution* made from toluene, tetrahydrofuran, paclitaxel and the copolymer can be used.

This paragraph is directed to an *organic solution* that is used in the *formation of a medical device* or a portion of the same (see paragraph [0189]), and does not pertain to a

suspension wherein copolymer and therapeutic agents are "commingled in a buffered solution" as alleged in the Office Action. In contrast, claim 1 is directed to a pharmaceutically acceptable *suspension* that contains a pharmaceutically active agent in a physiologically acceptable liquid medium for *delivery to a patient.*

In this regard, it is noted that claim 1 requires, *inter alia,* the step of combining (a) a pharmaceutically active agent with (b) previously formed polymer microparticles, in a physiologically acceptable liquid medium, to form a pharmaceutically acceptable *suspension*. The compositions of paragraph 190, on the other hand, are polymer *solutions* (i.e., a single liquid phase), as opposed to *suspensions* (i.e., compositions comprising a previously formed polymer microparticles, suspended within a liquid phase) as claimed in claim 1.

With respect to paragraph 0196 (to follow, emphasis added), this portion of Pinchuck et al. is non-anticipatory for reasons akin to those discussed above in connection with paragraph 190:

> If desired, a therapeutic agent of interest can be provided at the same time as the copolymer coating, for example, by adding it to a *copolymer melt* during thermoplastic processing or by adding it to a *copolymer solution* during solvent-based processing as discussed above. Alternatively, it can be added after the coating is formed as discussed further below.

The same is true for Example 2, which was cited in the Office Action.

The Office Action further asserts that "the microparticles are provided in an amount of an exemplified 1 wt%." However, it is respectfully submitted that none of the citations which are offered in support of this assertion appear to be concerned with microparticles at all, much less microparticles in this amount.

The Office Action also refers to dimensions of 0.5 to 50 microns in paragraph 195. However, these dimensions are *coating* thicknesses, rather than microparticle dimensions. Note from paragraph 0033 of the present specification that "microparticles" are small particles ranging in largest dimension from 0.01 to 1000 microns, and that they can be of any shape, including spherical, rod-shaped, irregularly shaped, etc. Hence, it is not seen what connection could possibly exist between a *coating* on a medical device, as described in paragraph 195 of Pinchuk et al., and a *microparticle-containing suspension* as presently claimed in claim 1.

It is further submitted that claim 1 requires the following specific elements in combination: (a) a pharmaceutically active agent and (b) a component comprising a metal or a polymer that is incompatible with the pharmaceutically active agent.

For at least the above reasons, it is respectfully submitted that claim 1 is not anticipated by Pinchuk et al. Claims 2-3, 7-15, 17, 37, and 40-42 depend either directly or indirectly from claim 1 and are therefore not anticipated by Pinchuk et al. for at least the same reasons as claim 1.

In view of the above, reconsideration and withdrawal of the rejection of claims 1-3, 7-15, 17, 37, and 40-42 under 35 U.S.C. 102(e) as being anticipated by Pinchuk et al. are respectfully requested.

Rejection of Claims 1-3, 7-15, 17, 37, and 40-42 under 35 U.S.C. 103(a)

Claims 1-3, 7-15, 17, 37, and 40-42 are presently rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. in view of U.S. Patent Application Publication No.2003/0073972 (Rosenman et al.).

With respect to Pinchuk et al., which is cited under the provisions of 35 U.S.C. § 102(e), please note that the assignee of Pinchuk et al. (Scimed Life Systems, Inc.) and the assignee of the present application are one and the same. 35 U.S.C. § 103(c) reads as follows: "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Statement concerning common ownership

In this connection, and in compliance with M.P.E.P. 706.02(I)(2), it is submitted that the present Application Serial No. 09/845,080 and U.S. Patent Application Publication No. 2002/0107330 A1 were, at the time the invention of Application Serial No. 09/845,080 was made, both owned by Scimed Life Systems, Inc. or subject to an obligation of assignment to Scimed Life Systems, Inc.

With respect to Rosenman et al., this reference is deficient in at least three ways.

First, as noted above, claim 1 requires, *inter alia,* the step of combining (a) a pharmaceutically active agent with (b) previously formed polymer microparticles, in a physiologically acceptable liquid medium, to form a pharmaceutically acceptable suspension. Rosenman et al., on the other hand, neither teaches nor suggests combining a pharmaceutically active agent with *previously formed* polymer microparticles, because the pharmaceutically active agent is *already encapsulated* within the microparticles. See, e.g., paragraph [0062] of Rosenman et al. ("therapeutic substance [is] encapsulated in ... bioabsorbable polymer microspheres.")

The examiner is apparently under the impression that, because the pharmaceutically active agent is encapsulated within the microparticles, it would be provided with protection against incompatible components. However, even assuming for the sake of argument that this is the case, the claimed invention is nevertheless dramatically different from the teachings of Rosenman et al. For example, rather than describing the *encapsulation* of pharmaceutically active agent for protection as taught in Rosenman et al., the pharmaceutically active agent in claim 1 is combined with *previously formed* polymer microparticles to achieve protection.

Second, claim 1 requires, *inter alia*, that the pharmaceutically acceptable suspension come into contact with an incompatible component of an endoluminal drug delivery catheter. In Rosenman et al., on the other hand the microspheres are placed inside "helical or dart-like implants" which are implanted into the myocardium or other body tissue. See Abstract. See also, paragraph [0062] ("the dart may be constructed of *a shell* 79 of polymer, ceramic, glass, elastomer and metal *that encases a central portion* 80 containing therapeutic material such as lyophilized therapeutic protein. The *central portion may be* a cast, compression molded or extruded reservoir of therapeutic substance or *therapeutic substance encapsulated in bioabsorbable polymers or bioabsorbable polymer microspheres.*")

Hence, although Rosenman et al. does appear to teach a catheter system for implanting the "helical or dart-like implants" (see Abstract), the microsphere-encapsulated therapeutic agent of Rosenman et al., is *inside the shell of the implant* and

thus does not *contact an incompatible component of an endoluminal drug delivery catheter* as required by claim 1.

Third, and as noted above, claim 1 requires the following elements in combination: (a) a pharmaceutically active agent and (b) a component comprising a metal or a polymer that is incompatible with the pharmaceutically active agent. Such a combination is neither taught nor suggested by Rosenman et al.

For at least the above reasons, it is respectfully submitted that claim 1 is unobvious in view of Rosenman et al. Claims 2, 3, 7-15, 17, 37, and 40-42 depend, either directly or indirectly, from claim 1 and are therefore unobvious over Rosenman et al. for at least the same reasons as is claim 1.

In view of the above, reconsideration and withdrawal of the rejection of claims 1-3, 7-15, 17, 37, and 40-42 under 35 U.S.C. 103(a) as being obvious over Pinchuk et al. in view of Rosenman et al. are respectfully requested.

Rejection of Claims 1, 2, 7-15, 17, 37 and 40-42 under 35 U.S.C. 103(a)

Claims 1, 2, 7-15, 17, 37 and 40-42 are presently rejected under 35 U.S.C. 103(a) as being unpatentable over either U.S. Patent No. 6,638,259 (Palasis et al.) or U.S. Patent No. 6,663,606 (Barry et al.) taken with Pinchuk et al. and Rosenman et al.

Claims 1, 2, 7-15, 17, 37 and 40-42 are patentable over Pinchuk et al. and Rosenman et al. for at least the reasons set forth in the prior section. Neither Palasis et al. nor Barry et al. make up for the above-noted deficiencies.

With respect to U.S. Patent No. 6,638,259 to Palasis et al., this reference was published after the filing of the present application and is thus being cited in the Office Action under the provisions of 35 U.S.C. § 102(e). However, it is noted that the assignee of Palasis et al. (Scimed Life Systems, Inc.) and the assignee of the present application are one and the same. 35 U.S.C. § 103(c) reads as follows: "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was

made, owned by the same person or subject to an obligation of assignment to the same person."

Statement concerning common ownership

In this connection, and in compliance with M.P.E.P. 706.02(I)(2), it is submitted that the present Application Serial No. 09/845,080 and U.S. Patent No. 6,638,259 to Palasis et al. were, at the time the invention of Application Serial No. 09/845,080 was made, both owned by Scimed Life Systems, Inc. or subject to an obligation of assignment to Scimed Life Systems, Inc.

Similarly, with respect to U.S. Patent No. 6,663,606 to Barry et al., this reference was published after the filing of the present application and is thus being cited under the provisions of 35 U.S.C. § 102(e). However, the assignee of Barry et al. (Scimed Life Systems, Inc.) and the assignee of the present application are one and the same. 35 U.S.C. § 103(c) reads as follows: "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Statement concerning common ownership

In this connection, and in compliance with M.P.E.P. 706.02(I)(2), it is submitted that the present Application Serial No. 09/845,080 and U.S. Patent No. 6,663,606 to Barry et al., at the time the invention of Application Serial No. 09/845,080 was made, both owned by Scimed Life Systems, Inc. or subject to an obligation of assignment to Scimed Life Systems, Inc.

For at least the above reasons, reconsideration and withdrawal of the rejection of Claims 1, 2, 7-15, 17, 37 and 40-42 under 35 U.S.C. 103(a) as being unpatentable over either Palasis et al. or Barry et al., taken with Pinchuk et al. and Rosenman et al. are respectfully requested.

Serial No.: 09/845,080

Double Patenting Rejection of Claims 1-3, 7-15, 17, 37 and 40-42

Claims 1-3, 7-15, 17, 37 and 40-42 are presently rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the *claims* of either U.S. Patent No. 6,638,259 (Palasis et al.) or U.S. Patent No. 6,663,606 (Barry et al.) taken with Pinchuk et al. and Rosenman et al.

Applicants respectfully disagree. Claims 1-3, 7-15, 17, 37 and 40-42 are patentable over Pinchuk et al. and Rosenman et al. for at least the reasons set forth above, and the claims of Palasis et al. and Barry et al. do not make up for the deficiencies in Pinchuk et al. and Rosenman et al.

For example, as noted above Pinchuk et al. and Rosenman et al. neither teach nor suggest a step of combining (a) a pharmaceutically active agent with (b) previously formed polymer microparticles, in a physiologically acceptable liquid medium, to form a pharmaceutically acceptable suspension.

The claims of Palasis et al. and Barry et al. are likewise deficient. In particular, the claims of Palasis et al. and Barry et al. do not describe the use of *microparticles* to protect the pharmaceutical effectiveness of a pharmaceutically active agent from a component that is incompatible with the pharmaceutically active agent. Rather the claims of Palasis et al. and Barry et al. make use of a *layer* of polymeric material for this purpose.

For at least the above reasons, 1-3, 7-15, 17, 37 and 40-42 are patentable over the claims of either Palasis et al. or Barry et al., taken with Pinchuk et al. and Rosenman et al.

Hence, reconsideration and withdrawal of the rejection of claims 1-3, 7-15, 17, 37 and 40-42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of either Palasis et al. or Barry et al. taken with Pinchuk et al. and Rosenman et al. are respectfully requested.

Serial No.: 09/845,080

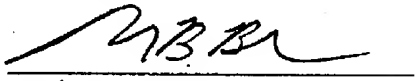
CONCLUSION

Applicants submit that this application is in condition for allowance, early notification of which is earnestly solicited. The Examiner is encouraged to contact the undersigned at (703) 433-0510 to discuss any outstanding issues in this case.

FEES

The Office is authorized to charge any fees required in connection with this application to deposit account number 50-1047.

Respectfully submitted,



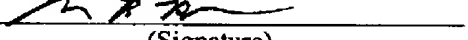
David B. Bonham
Registration No. 34,297

Attorney for Applicant
Mayer Fortkort & Williams, PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362

Certificate of Facsimile Transmission

I hereby certify that this correspondence is being sent to the United States Patent and Trademark office via Facsimile to: 703-872-9306 on April 9, 2004.

David B. Bonham
(Printed Name of Person Mailing Correspondence)



(Signature)